THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:

HOFER-AMMANN, Christina et al.	Confirmation No.: 8957
Application No.: 10/564,452	Group Art Unit: 1781
Filing Date: January 12, 2006	Examiner: GWARTNEY, Elizabeth A.
For: HIGH FIBRE HIGH CALORIE LIQUID OR POWDERED NUTRITIONAL COMPOSITION	Attorney Docket No. 7444-US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S APPEAL BRIEF

Sir:

Appellant submits this Appeal Brief in support of the Notice of Appeal filed on February 22, 2010. This Appeal is taken from the Final Rejection dated December 1, 2009 and the Advisory Action dated February 18, 2010.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Nestec S.A. by virtue of an Assignment dated April 15, 2010, and recorded at reel 024237, frame 0718 in the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellant's legal representative and the Assignee of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF CLAIMS

Claims 1-2 and 8-15 are pending in the above-identified patent application. Claims 3-7 were previously canceled without prejudice or disclaimer. Claims 1-2 and 8-15 stand rejected. Therefore, Claims 1-2 and 8-15 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

IV. STATUS OF AMENDMENTS

On June 26, 2009, the Examiner mailed a non-final Office Action in which Claims 1-2, 5 and 8-15 were rejected as being obvious under 35 U.S.C. §103(a). Appellant filed a Response to the non-final Office Action on August 11, 2009, in which Appellant amended the claims and argued against the obviousness rejection. The Examiner mailed a final Office Action on December 1, 2009, in which the obviousness rejections were maintained. Appellant filed a Response to the final Office Action on January 20, 2010, in which Appellant amended the claims, submitted a Declaration, and argued against the obviousness rejection. The Examiner mailed an Advisory Action on February 18, 2010. Appellant filed a Notice of Appeal on February 22, 2010. A copy of the non-final Office Action, final Office Action and Advisory Action are attached hereto as Exhibits A, B and C, respectively.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to the drawings and specification for each of the independent claims and each means plus function claim may be found in Appendix B to this Brief.

Independent Claim 1 is directed to a liquid or powdered and reconstitutable nutritional composition comprising 4.5 to 6g protein/100ml composition (page 7, lines 29-32), a source of digestible carbohydrates (page 6, line 35-page 7, line 17) and a source of dietary fiber (page 5, line 18-page 6, line 34), having an energy density of 1.3-1.8 kcal/ml (Abstract; page 9, lines 1-2) and dietary fiber in an amount of more than 2.5g/100ml (page 3, lines 8-12), wherein the source of dietary fiber comprises 20-40% by weight acacia gum (page 5, line 26-page 6, line 28), 30-60% by weight of pea outer fiber (page 5, lines 26-31; page 5, line 18-page 6, line 34) and 20-40% by weight of fructooligasaccharides (page 5, lines 26-31; page 5, line 18-page 6, line 34), wherein the composition comprises a viscosity of 30 – 80 mPas (page 9, lines 23-25).

Independent Claim 10 is directed to a method for improving the digestive tract and bowel function of a patient requiring same, the method comprising administering to the patient a liquid or powdered and reconstitutable nutritional composition comprising 4.5 to 6g protein/100ml composition (page 7, lines 29-32), a source of digestible carbohydrates (page 6, line 35-page 7, line 17) and a source of dietary fiber (page 5, line 18-page 6, line 34), having an energy density of 1.3-1.8 kcal/ml (Abstract; page 9, lines 1-2) and dietary fiber in an amount of more than 2.5g/100ml (page 3, lines 8-12), wherein the source of dietary fiber comprises 20-40% by weight acacia gum (page 5, line 26-page 6, line 28), 30-60% by weight of pea outer fiber (page 5, lines 26-31; page 5, line 18-page 6, line 34) and 20-40% by weight of fructooligasaccharides (page 5, lines 26-31; page 5, line 18-page 6, line 34), wherein the composition comprises a viscosity of 30 – 80 mPas (page 9, lines 23-25).

Independent Claim 11 is directed to a method for enhancing mucosal barrier function in a patient requiring same, the method comprising administering to the patient a liquid or powdered and reconstitutable nutritional composition comprising 4.5 to 6g protein/100ml composition (page 7, lines 29-32), a source of digestible carbohydrates (page 6, line 35-page 7, line 17) and a source of dietary fiber (page 5, line 18-page 6, line 34) having an energy density of 1.3-1.8 kcal/ml (Abstract; page 9, lines 1-2) and dietary fiber in an amount of more than 2.5g/100ml

(page 3, lines 8-12), wherein the source of dietary fiber comprises 20-40% by weight acacia gum (page 5, line 26-page 6, line 28), 30-60% by weight of pea outer fiber (page 5, lines 26-31; page 5, line 18-page 6, line 34) and 20-40% by weight of fructooligasaccharides (page 5, lines 26-31; page 5, line 18-page 6, line 34), wherein the composition comprises a viscosity of 30 – 80 mPas (page 9, lines 23-25).

Independent Claim 12 is directed to a method for promoting gut health or comfort in an elderly patient in need of same, the method comprising administering to the patient a liquid or powdered and reconstitutable nutritional composition comprising 4.5 to 6g protein/100ml composition (page 7, lines 29-32), a source of digestible carbohydrates (page 6, line 35-page 7, line 17) and a source of dietary fiber (page 5, line 18-page 6, line 34), having an energy density of 1.3-1.8 kcal/ml (Abstract; page 9, lines 1-2) and dietary fiber in an amount of more than 2.5g/100ml (page 3, lines 8-12), wherein the source of dietary fiber comprises 20-40% by weight acacia gum (page 5, line 26-page 6, line 28), 30-60% by weight of pea outer fiber (page 5, lines 26-31; page 5, line 18-page 6, line 34) and 20-40% by weight of fructooligasaccharides (page 5, lines 26-31; page 5, line 18-page 6, line 34), wherein the composition comprises a viscosity of 30 – 80 mPas (page 9, lines 23-25).

Independent Claim 13 is directed to a method for preparing a nutritional composition, the method comprising: mixing a liquid or powdered and reconstitutable nutritional composition comprising 4.5 to 6g protein/100ml composition (page 7, lines 29-32), a source of digestible carbohydrates (page 6, line 35-page 7, line 17) and a source of dietary fiber (page 5, line 18-page 6, line 34), having an energy density of 1.3-1.8 kcal/ml (Abstract; page 9, lines 1-2) and dietary fiber in an amount of more than 2.5g/100ml (page 3, lines 8-12), wherein the source of dietary fiber comprises 20-40% by weight acacia gum (page 5, line 26-page 6, line 28), 30-60% by weight of pea outer fiber (page 5, lines 26-31; page 5, line 18-page 6, line 34) and 20-40% by weight of fructooligasaccharides (page 5, lines 26-31; page 5, line 18-page 6, line 34), and hydrating the components to provide a liquid mixture, wherein the composition comprises a viscosity of 30 – 80 mPas (page 9, lines 23-25).

Independent Claim 14 is directed to a method for maintaining or restoring a well-balanced gut flora, the method comprising administering to an individual in need of same a liquid or powdered and reconstitutable nutritional composition comprising 4.5 to 6g protein/100ml composition (page 7, lines 29-32), a source of digestible carbohydrates (page 6,

line 35-page 7, line 17) and a source of dietary fiber (page 5, line 18-page 6, line 34), having an energy density of 1.3-1.8 kcal/ml (Abstract; page 9, lines 1-2) and dietary fiber in an amount of more than 2.5g/100ml (page 3, lines 8-12), wherein the source of dietary fiber comprises 20-40% by weight acacia gum (page 5, line 26-page 6, line 28), 30-60% by weight of pea outer fiber (page 5, lines 26-31; page 5, line 18-page 6, line 34) and 20-40% by weight of fructooligasaccharides (page 5, lines 26-31; page 5, line 18-page 6, line 34), wherein the composition comprises a viscosity of 30 – 80 mPas (page 9, lines 23-25).

Independent Claim 15 is directed to a method for enhancing mucosal function in a human individual in need of same, the method comprising administering to the human individual a liquid or powdered and reconstitutable nutritional composition comprising 4.5 to 6g protein/100ml composition (page 7, lines 29-32), a source of digestible carbohydrates (page 6, line 35-page 7, line 17) and a source of dietary fiber (page 5, line 18-page 6, line 34), having an energy density of 1.3-1.8 kcal/ml (Abstract; page 9, lines 1-2) and dietary fiber in an amount of more than 2.5g/100ml (page 3, lines 8-12), wherein the source of dietary fiber comprises 20-40% by weight acacia gum (page 5, line 26-page 6, line 28), 30-60% by weight of pea outer fiber (page 5, lines 26-31; page 5, line 18-page 6, line 34) and 20-40% by weight of fructooligasaccharides (page 5, lines 26-31; page 5, line 18-page 6, line 34), wherein the composition comprises a viscosity of 30 – 80 mPas (page 9, lines 23-25).

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the references numerals and citations below, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1-2 and 8-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over WO 02/39834 to Spivey-Krobath et al. ("*Spivey-Krobath*") in view of U.S. Patent No. 6,489,310 to Brassart et al. ("*Brassart*"). Copies of *Spivey-Krobath* and *Brassart* as attached hereto as Exhibits D and E, respectively, in the Evidence Appendix.

VII. ARGUMENT

A. LEGAL STANDARDS

Obviousness under 35 U.S.C. § 103

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

> whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made…The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art…Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness…Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q. 2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q. 2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome "by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings." *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). "If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference or references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *In re Fine*, 837 F.2d 1071, 5, U.S.P.Q.2d 1596 (Fed. Cir. 1988). Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Finally, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q., 580 (CCPA 1974).

Further, the Federal Circuit has held that it is "impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

Moreover, the Federal Circuit has held that "obvious to try" is not the proper standard under 35 U.S.C. §103. *Ex parte Goldgaber*, 41 U.S.P.Q.2d 1172, 1177 (Fed. Cir. 1996). "An-obvious-to-try situation exists when a general disclosure may pique the scientist curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued." *In re Eli Lilly and Co.*, 14 U.S.P.Q.2d 1741, 1743 (Fed. Cir. 1990).

Of course, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant." *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

B. THE CLAIMED INVENTION

Independent Claim 1 is directed to a liquid or powdered and reconstitutable nutritional composition. The composition includes 4.5 to 6g protein/100ml composition, a source of digestible carbohydrates, a source of dietary fiber, and an energy density of 1.3-1.8 kcal/ml. The dietary fiber is provided in an amount of more than 2.5g/100ml, and includes 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides. The composition has a viscosity of 30 – 80 mPas.

Independent Claim 10 is directed to a method for improving the digestive tract and bowel function of a patient requiring same, the method including administering to the patient a liquid or

powdered and reconstitutable nutritional composition. The composition includes 4.5 to 6g protein/100ml composition, a source of digestible carbohydrates, a source of dietary fiber, and an energy density of 1.3-1.8 kcal/ml. The dietary fiber is provided in an amount of more than 2.5g/100ml, and includes 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides. The composition has a viscosity of 30 – 80 mPas.

Independent Claim 11 is directed to a method for enhancing mucosal barrier function in a patient requiring same, the method including administering to the patient a liquid or powdered and reconstitutable nutritional composition. The composition includes 4.5 to 6g protein/100ml composition, a source of digestible carbohydrates, a source of dietary fiber, and an energy density of 1.3-1.8 kcal/ml. The dietary fiber is provided in an amount of more than 2.5g/100ml, and includes 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides. The composition has a viscosity of 30 – 80 mPas.

Independent Claim 12 is directed to a method for promoting gut health or comfort in an elderly patient in need of same, the method including administering to the patient a liquid or powdered and reconstitutable nutritional composition. The composition includes 4.5 to 6g protein/100ml composition, a source of digestible carbohydrates, a source of dietary fiber, and an energy density of 1.3-1.8 kcal/ml. The dietary fiber is provided in an amount of more than 2.5g/100ml, and includes 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides. The composition has a viscosity of 30 – 80 mPas.

Independent Claim 13 is directed to a method for preparing a nutritional composition, the method including mixing a liquid or powdered and reconstitutable nutritional composition. The composition includes 4.5 to 6g protein/100ml composition, a source of digestible carbohydrates, a source of dietary fiber, and an energy density of 1.3-1.8 kcal/ml. The dietary fiber is provided in an amount of more than 2.5g/100ml, and includes 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides. The composition has a viscosity of 30 – 80 mPas.

Independent Claim 14 is directed to a method for maintaining or restoring a well-balanced gut flora, the method including administering to an individual in need of same a liquid or powdered and reconstitutable nutritional composition. The composition includes 4.5 to 6g

protein/100ml composition, a source of digestible carbohydrates, a source of dietary fiber, and an energy density of 1.3-1.8 kcal/ml. The dietary fiber is provided in an amount of more than 2.5g/100ml, and includes 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides. The composition has a viscosity of 30 – 80 mPas.

Independent Claim 15 is directed to a method for enhancing mucosal function in a human individual in need of same, the method including administering to the human individual a liquid or powdered and reconstitutable nutritional composition. The composition includes 4.5 to 6g protein/100ml composition, a source of digestible carbohydrates, a source of dietary fiber, and an energy density of 1.3-1.8 kcal/ml. The dietary fiber is provided in an amount of more than 2.5g/100ml, and includes 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides. The composition has a viscosity of 30 – 80 mPas.

C. THE REJECTION OF CLAIMS 1-2 AND 8-15 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS

Appellant respectfully submits that the obviousness rejection of Claims 1-2 and 8-15 should be reversed because the Examiner has failed to establish a *prima facie* case of obviousness. In the final Office Action, the Examiner asserts that the combination of *Spivey-Krobath* and *Brassart* renders the claimed subject matter obvious. See, final Office Action, pages 2-10. However, the Examiner has failed to establish a *prima facie* case of obviousness for several reasons. For example, the *Declaration* submitted on January 20, 2010 demonstrates secondary considerations that overcome the obviousness rejection. In addition, the cited references fail to disclose each and every element of the present claims.

1. The *Declaration* demonstrates secondary considerations that overcome the obviousness rejection

Independent Claims 1 and 10-15 recite, in part, a nutritional composition comprising 4.5 to 6g protein/100ml composition. Independent Claims 1 and 10-15 further recite, in part, a dietary fiber comprising 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides. In addition, independent Claims 1 and 10-15 recite, in part, that the composition comprises a viscosity of 30 – 80 mPas. Malnutrition or gastro-intestinal disorders, more generally gut-discomfort or pain, may simply be the consequence of unhealthy or unbalanced nutritional behavior. However, malnutrition may also affect perfectly healthy people, be it due to increased energy expenditure, as is the case with athletes or other sportsmen following intensive physical exercise, be it in other circumstances such as pregnancy. The occurrence of malnutrition in various situations during life, in particular with elderly or ill people, has thus led mainly to high calorie and high nutrient compositions. Consumption of such compositions, however, was often problematic, especially in patients with unbalanced gut flora and with gut impairment, because of gut pain or discomfort. See, specification, page 1, line 20-page 3, line 6.

Appellant previously submitted a Declaration under 37 C.F.R. §1.132 ("*Declaration*" attached hereto as Exhibit F) that demonstrates the nonobviousness of the claimed invention with respect to the prior art. Specifically, the *Declaration* summarizes a controlled study performed by Appellant that demonstrates the surprising and unexpected tolerability of a composition having an increased amount of fiber that is nearly identical to the presently claimed composition as compared to a similar composition having a lower amount of fiber. As is demonstrated by the study discussed in Exhibit 1 of the *Declaration*, the presently claimed compositions have been found not to promote any undesired abdominal symptoms due to the increased amount of fiber. Indeed, the study discussed in the *Declaration* demonstrates that presently claimed low viscosity, high fiber compositions resulted in clinical compliance similar to that of a similar, non-fiber product and is equally well tolerated.

As supported in the *Declaration*, Appellant has surprisingly found that a nutritional composition including 4.5 to 6g protein/100ml composition and acacia gum as a soluble fiber in addition to pea outer fiber and fructooligosaccharides demonstrated good shelf-stability for 8 months and was judged to have a good taste. See, specification, Example at pages 12-15. The composition was rich in fiber and improved intestinal transit, gut flora and gut comfort. See, specification, Example, pages 12-15. Accordingly, the claimed invention provides a nutritional

composition that has a high energy content and improves digestive tract health. The presently claimed compositions also provide the advantage of a surprisingly low viscosity that results from use of the claimed fiber blend. As discussed in the *Declaration*, despite the high proportion of soluble non-starch polysaccharides and oligosaccharides, and the high amount of total fiber of the compositions, the compositions have a surprisingly low viscosity and are surprisingly well tolerated.

Further, the *Declaration* also describes the synergistic effect that is surprisingly observed between fructooligosaccharides and acacia gum on the bifidogenic effect. As is described in detail in the *Declaration* at Exhibit 4, using blends of fructooligosaccharides and acacia gum, an effective dose of prebiotic can be optimized in order to reduce potential abdominal discomfort related to the intake of fructooligosaccharides. Accordingly, not only does the *Declaration* demonstrate that the present compositions are as well tolerated as a similar, non-fiber composition, but the *Declaration* also demonstrates that using blends of fructooligosaccharides and acacia gum further reduces potential abdominal discomfort typically associate with the intake of fructooligosaccharides.

With respect to the present disclosure, it has been surprisingly found that a nutritional composition including 4.5 to 6g protein/100ml composition and acacia gum as a soluble fiber in addition to pea outer fiber and fructooligosaccharides demonstrated good shelf-stability for 8 months and was judged to have a good taste. The composition was rich in fiber and improved intestinal transit, gut flora and gut comfort. Accordingly, the claimed invention provides a nutritional composition that has a high energy content and improves digestive tract health. The presently claimed compositions also provide the advantage of a surprisingly low viscosity that results from use of the claimed fiber blend. Despite the high proportion of soluble non-starch polysaccharides and oligosaccharides, and the high amount of total fiber of the compositions, the compositions have a surprisingly low viscosity and are surprisingly well tolerated.

Referring more specifically to the exhibits of the *Declaration*, Exhibit 1 is a summary of a controlled study demonstrating the tolerability of a composition having increased amounts of fiber similar to the presently claimed composition, as compared to a similar, non-fiber composition with known tolerability. The study performed was a double blind placebo controlled and randomized study having eighty-nine elderly volunteers that were asked to answer questionnaires on gut comfort and well-being. The elderly were allocated to two treatment

groups in equal numbers. One group received Clinutren® 1.5 as an oral supplement and the other group received Clinutren® 1.5 Fiber as an oral supplement (the compositions of which are attached hereto as Exhibits 2 and 3 of the *Declaration*, respectively). The oral supplements were given in 200 ml cups twice a day targeting a daily intake equal to 400 ml and 600 Kcal during a five week period.

Before, during and after the study period summarized at Exhibit 1 of the *Declaration*, various anthropometric, biochemical, and fecal microbiological measurements were taken. All adverse events that occurred during the study were reported and recorded regardless of severity or relation to the nutritional intervention. The volunteers also filled out an eight-question questionnaire on gut comfort and well-being four times over a six week period.

As is described in detail in the summary of Exhibit 1 of the *Declaration*, there were no reported negative effects of either of the oral supplements. In particular, the increased fiber supplement (Clinutren® 1.5 Fiber), which includes a similar fiber content, including pea outer fiber, to the presently claimed compositions, did not promote any undesired abdominal symptoms. Accordingly, the increased fiber supplement (Clinutren® 1.5 Fiber) was surprisingly as well tolerated as a similar, non-fiber composition (Clinutren® 1.5).

Further, as mentioned above and attached hereto as Exhibit 4 of the *Declaration*, is a summary that describes a randomized, double-blind study used to determine if a blend of fructooligosaccharides and acacia gum stimulates intestinal growth of bifidobacteria more effectively than each of the carbohydrates alone. The study performed utilized ninety-six healthy volunteers that were divided into three groups. A first group consumed 200 ml/day of skimmed milk with fructooligosaccharides (6g/day). A second group consumed 200 ml/day of skimmed milk with acacia gum (6g/day). The third group consumed 200 ml/day of skimmed milk with fructooligosaccharides and acacia gum ((3g fructooligosaccharides + 3g acacia gum)/day).

As described in Exhibit 4 of the *Declaration*, a synergy was observed between fructooligosaccharides and acacia gum on the bifidogenic effect. Accordingly, using blends of fructooligosaccharides and acacia gum, an effective dose of prebiotic can be optimized in order to reduce potential abdominal discomfort related to the intake of fructooligosaccharides.

In the Advisory Action, the Examiner asserts that "[w]hile [Appellant] demonstrate[s] that a nutritional composition comprising high fiber (Clinutren® 1.5 Fibre) was as well tolerated as a similar, non-fiber composition (Clinutren® 1.5), [Appellant] ha[s] not shown a comparison

with the closest prior art, i.e. *Spivey-Krobath* et al." See, Advisory Action, page 3, lines 4-7. The Examiner also asserts that Appellant has "not provided any evidence to show that the nutritional composition of modified *Spivey-Krobath* et al. would not exhibit the same benefits as the presently claimed invention." See, Advisory Action, page 3, lines 15-17. Appellant respectfully disagrees.

Instead, Appellant respectfully submits that the comparison made in the *Declaration* regarding a nutritional composition comprising high fiber (Clinutren® 1.5 Fibre) as compared to a similar, non-fiber composition (Clinutren® 1.5), is an even more direct comparison than the present claims and *Spivey-Krobath*. Indeed, as shown in as Exhibits 2 and 3 of the *Declaration*, Clinutren® 1.5 Fibre and Clinutren® 1.5 are similar compositions that differ with respect to the fiber content. The studies performed by Appellant indicate that increased fiber supplement (Clinutren® 1.5 Fiber), which includes a similar fiber content, including pea outer fiber, to the presently claimed compositions, did not promote any undesired abdominal symptoms. Accordingly, the increased fiber supplement (Clinutren® 1.5 Fiber) was surprisingly as well tolerated as a similar, non-fiber composition (Clinutren® 1.5).

Therefore, the comparison between Clinutren® 1.5 Fibre, which includes a similar fiber content, including pea outer fiber, to the presently claimed compositions, and Clinutren® 1.5 is an even better comparison than the present claims and *Spivey-Krobath*, which fails to disclose or suggest each and every element of the present claims including, for example, protein content, the source of dietary fiber, and the composition viscosity, as will be discussed in detail below. Accordingly, Appellant submits that a comparison of the present claims and *Spivey-Krobath* would be less informative than the comparison between Clinutren® 1.5 Fibre and Clinutren® 1.5 presented by Appellant.

2. The Cited References Fail to Disclose Each and Every Element of the Present Claims

As discussed above, independent Claims 1 and 10-15 recite, in part, a nutritional composition comprising 4.5 to 6g protein/100ml composition. Independent Claims 1 and 10-15 further recite, in part, a dietary fiber comprising 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides. In addition,

independent Claims 1 and 10-15 recite, in part, that the composition comprises a viscosity of 30 – 80 mPas. In contrast, Appellant respectfully submits that the cited references alone or in combination fail to disclose or suggest every element of independent Claims 1 and 10-15.

Malnutrition or gastro-intestinal disorders, more generally gut-discomfort or pain, may simply be the consequence of unhealthy or unbalanced nutritional behavior. However, malnutrition may also affect perfectly healthy people, be it due to increased energy expenditure, as is the case with athletes or other sportsmen following intensive physical exercise, be it in other circumstances such as pregnancy. The occurrence of malnutrition in various situations during life, in particular with elderly or ill people, has thus led mainly to high calorie and high nutrient compositions. Consumption of such compositions, however, was often problematic, especially in patients with unbalanced gut flora and with gut impairment, because of gut pain or discomfort. See, specification, page 1, line 20-page 3, line 6. In contrast, Appellant submits that the cited references fail to disclose or suggest each and every element of the present claims.

Spivey-Krobath and *Brassart* alone or in combination fail to disclose or suggest a nutritional composition comprising 4.5 to 6g protein/100ml composition as required by independent Claims 1 and 10-15. *Spivey-Krobath* and *Brassart* alone or in combination also fail to disclose or suggest a source of dietary fiber comprising a specific blend of 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligosaccharides. Finally, *Spivey-Krobath* and *Brassart* alone or in combination fail to disclose or suggest that the nutritional composition comprises a viscosity of 30 – 80 mPas as required by independent Claims 1 and 10-15.

Spivey-Krobath is primarily directed toward a nutritional composition for the prevention or treatment of an immune condition. The only reference to specific amounts of protein at any place in *Spivey-Krobath* is in Table 1 on page 10 where it is specified that the composition contains either 10.5 or 7.0 g protein/100ml of composition dependent on the desired energy content of the composition, which falls outside the claimed range. See, *Spivey-Krobath,* Table 1. Further, *Spivey-Krobath* also fails to teach or suggest any viscosity for its nutritional composition. Moreover, *Spivey-Krobath* fails to teach the use of pea outer fiber. As such, *Spivey-Krobath* fails to disclose or suggest the specific combination of dietary fiber that comprises 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by

weight of fructooligosaccharides to provide a composition having a viscosity of 30 – 80 mPas in accordance with the present claims.

Brassart is entirely directed toward an enteral composition that contains a protein source, a lipid source, a carbohydrate source and a fiber blend. See, *Brassart*, Abstract. However, the only place in the disclosure of *Brassart* that discusses specific amounts of protein are in the examples, where 3.8g protein/100ml composition was used, which is below the claimed range. See, *e.g.*, *Brassart*, Example 1. Further, *Brassart* fails to disclose or suggest the presently claimed viscosity of the composition. Instead, *Brassart* discloses that its enteral composition may have a viscosity of less than about 12 cp at room temperature, which is outside the claimed range. See, *Brassart*, column 6, lines 40-44. Finally, *Brassart* fails to teach or suggest the use of acacia gum and therefore is deficient with respect to the claimed source of dietary fiber.

Appellant respectfully submits that *Spivey-Krobath* clearly does not disclose the "identical" composition to that presently claimed. Instead, as Appellant has already pointed out, *Spivey-Krobath* and *Brassart* fail to disclose the presently claimed compositions having certain protein and fibers amounts. Of course, the amount of components contained in a composition can greatly affect the viscosity of the composition. Because the cited references fail to disclose or suggest each and every element of the present claims, Appellant respectfully submits that it is improper for the Examiner to allege that the compositions of the cited references have viscosity ranges that are "identical" to the viscosities of the claimed compositions.

In addition, to satisfy the test for inherency, the Examiner would be required to show that the compositions of *Spivey-Krobath* and *Brassart* necessarily (*i.e.*, always or automatically) provide for compositions having a viscosity of about 30-80 mPas. That condition simply is not met under the present circumstances, especially in view of the fact that the claimed nutritional compositions and compositions of the cited references are not the same. For example, neither *Spivey-Krobath* and *Brassart* teach the specific dietary fiber blends in accordance with the present claims. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. See, MPEP 2112. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

In the Advisory Action, the Examiner asserts that "[g]iven that *Spivey-Krobath* et al. and *Brassart* et al. both disclose protein in amounts that overlap or would be expected to have the same properties as the amounts presently claimed, it is clear that the references as combined

disclose compositions identical to that presently claimed. Thus, given that *Spivey-Krobath* et al. and *Brassart* et al disclose compositions identical to that presently claimed, it is clear that the compositions would inherently posses a viscosity of about 30-80 mPas." See, Advisory Action, page 4, lines 3-8. Appellant respectfully disagrees.

As clearly stated above, the only reference to specific amounts of protein at any place in *Spivey-Krobath* is in Table 1 on page 10 where it is specified that the composition contains either 10.5 or 7.0 g protein/100ml of composition dependent on the desired energy content of the composition, which falls outside the claimed range. See, *Spivey-Krobath,* Table 1 (emphasis added). Further, the only place in the disclosure of *Brassart* that discusses specific amounts of protein are in the examples, where 3.8g protein/100ml composition was used, which is below the claimed range. See, *e.g.*, *Brassart*, Example 1 (emphasis added). Accordingly, for at least this reason, it is clear that the cited references do not disclose identical compositions to the presently claimed compositions. For the Examiner to assert that the cited references disclose "identical" compositions is erroneous.

Appellant respectfully submits that the Examiner has improperly applied hindsight reasoning by selectively piecing together teachings of each of the references in an attempt to recreate what the claimed invention discloses. As the Federal Circuit explained, "the mere fact that the prior art may be modified in the manner suggested by the examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, at 1783-17. The claims must be viewed as a whole as defined by the claimed invention and not dissected into discrete elements to be analyzed in isolation. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983); *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995).

In sum, the cited references alone or in combination fail to disclose or suggest each and every element of independent Claims 1 and 10-15. Moreover, the cited references fail to even recognize the advantages, unexpected benefits and/or properties of nutritional product in accordance with the present claims and as described in detail in the attached Exhibits.

For at least the reasons discussed above, Appellant respectfully submits that independent Claims 1 and 10-15, along with the claims that depend from Claims 1 and 10-15, are novel, nonobvious and distinguishable from the cited references.

Accordingly, Appellant respectfully requests that the obviousness rejection of Claims 1-2 and 8-15 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

VIII. CONCLUSION

Appellant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103(a) with respect to the rejections of Claims 1-2 and 8-15. Accordingly, Appellant respectfully submits that the obviousness rejections are erroneous in law and in fact and should, therefore, be reversed by this Board.

A check in the amount of $540 is submitted herewith to cover the cost of the Appeal Brief. The Director is authorized to charge any additional fees that may be required, or to credit any overpayment to Deposit Account No. 50-4498 in the name of Nestle Nutrition.

Respectfully submitted,

By: /gml/
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Dated: April 22, 2010

CLAIMS APPENDIX

PENDING CLAIMS ON APPEAL OF U.S. PATENT APPLICATION SERIAL NO. 10/564,452

1. A liquid or powdered and reconstitutable nutritional composition comprising 4.5 to 6g protein/100ml composition, a source of digestible carbohydrates and a source of dietary fiber, having an energy density of 1.3-1.8 kcal/ml and dietary fiber in an amount of more than 2.5g/100ml, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas.

2. The composition according to claim 1 wherein the energy density is between 1.4-1.6 kcal/ml.

8. The composition according to claim 1 comprising a source of lipids.

9. The composition according to claim 1 wherein the composition is clinically free of lactose.

10. A method for improving the digestive tract and bowel function of a patient requiring same, the method comprising administering to the patient a liquid or powdered and reconstitutable nutritional composition comprising 4.5 to 6g protein/100ml composition, a source of digestible carbohydrates and a source of dietary fiber, having an energy density of 1.3-1.8 kcal/ml and dietary fiber in an amount of more than 2.5g/100ml, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas.

11. A method for enhancing mucosal barrier function in a patient requiring same, the method comprising administering to the patient a liquid or powdered and reconstitutable nutritional composition comprising 4.5 to 6g protein/100ml composition, a source of digestible carbohydrates and a source of dietary fiber, having an energy density of 1.3-1.8 kcal/ml and dietary fiber in an amount of more than 2.5g/100ml, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas.

12. A method for promoting gut health or comfort in an elderly patient in need of same, the method comprising administering to the patient a liquid or powdered and reconstitutable nutritional composition comprising 4.5 to 6g protein/100ml composition, a source of digestible carbohydrates and a source of dietary fiber, having an energy density of 1.3-1.8 kcal/ml and dietary fiber in an amount of more than 2.5g/100ml, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas.

13. A method for preparing a nutritional composition, the method comprising:

mixing a liquid or powdered and reconstitutable nutritional composition comprising 4.5 to 6g protein/100ml composition, a source of digestible carbohydrates and a source of dietary fiber, having an energy density of 1.3-1.8 kcal/ml and dietary fiber in an amount of more than 2.5g/100ml, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides, and

hydrating the components to provide a liquid mixture, wherein the composition comprises a viscosity of 30 – 80 mPas.

14. A method for maintaining or restoring a well-balanced gut flora, the method comprising administering to an individual in need of same a liquid or powdered and reconstitutable nutritional composition comprising 4.5 to 6g protein/100ml composition, a source of digestible carbohydrates and a source of dietary fiber, having an energy density of 1.3-1.8 kcal/ml and dietary fiber in an amount of more than 2.5g/100ml, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas.

15. A method for enhancing mucosal function in a human individual in need of same, the method comprising administering to the human individual a liquid or powdered and reconstitutable nutritional composition comprising 4.5 to 6g protein/100ml composition, a source of digestible carbohydrates and a source of dietary fiber, having an energy density of 1.3-1.8 kcal/ml and dietary fiber in an amount of more than 2.5g/100ml, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligasaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas.

EVIDENCE APPENDIX

EXHIBIT A: Non-Final Office Action mailed June 26, 2009

EXHIBIT B: Final Office Action mailed December 1, 2009

EXHIBIT C: Advisory Action mailed February 18, 2010

EXHIBIT D: WO 02/39834 to Spivey-Krobath et al. ("*Spivey-Krobath*")

EXHIBIT E: U.S. Patent No. 6,489,310 to Brassart et al. ("*Brassart*")

EXHIBIT F: *Declaration* under 37 CFR 1.132

RELATED PROCEEDINGS APPENDIX

None.